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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,836	06/27/2003	Vinayak D. Bhat	020460-001691US	8416

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EXAMINER

IZQUIERDO, DAVID A

ART UNIT PAPER NUMBER

3738

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/607,836	Applicant(s) BHAT ET AL.	
	Examiner David A. Izquierdo	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7,12,14,20-23,25,28,37 and 39-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,12,14,20-23,25,28,37 and 39-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/27/03, 04/12/04, 11/26/04, 04/08/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-7, 12, 14, 20-23, 25, 28, 37, and 39-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (U.S. Patent Number 6,939,375) in view of Toner et al. (U.S. Patent Application Publication Number 2004/0180039). Sirhan et al. discloses an apparatus and method for controlled substance delivery comprising:

- An expandable stent structure with at least one source of at least one therapeutic capable agent and a rate controlling element covering a portion of the source (col. 3, lines 60-67; col. 5, lines 46-48).
- The release of at least one therapeutic agent capable of inhibiting restenosis (col. 3, lines 15-20).

however Sirhan et al. fails to specifically disclose the use of pimecrolimus as the therapeutic capable agent and the use of parylene as a rate controlling element. Toner et al. teaches both the use of pimecrolimus as a therapeutic capable agent for inhibition of restenosis (paragraph 16, line 20) and the use of parylene as a rate controlling element (paragraph 72, lines 20-23). It would have been obvious to one of ordinary skill in the art to combine the teaching of pimecrolimus and parylene, as taught by Toner et al., to a medical apparatus as per Sirhan et al, the motivation to combine being that pimecrolimus aides in the inhibition of restenosis and

Art Unit: 3738

polyene serves as a control release vehicle for therapeutic capable agents, as found in Toner et al. (paragraph 16, line 20; paragraph 71, lines 1-6).

NOTE: The current Application claims benefit to Parent Application filed prior to the effective file date of Sirhan et al (2/13/01) and Toner et al. (3/10/03) but a review of the Parent Applications shows the currently claimed subject matter only receives the benefit to Provisional Application 60/472,536 (05/21/03).

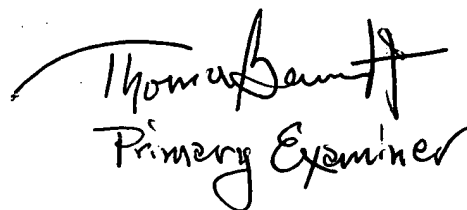
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Izquierdo whose telephone number is 571-272-1943. The examiner can normally be reached on Monday through Friday from 8:00 am until 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAI


Thomas Baumhoff
Primary Examiner